

**REMARKS**

Claims 1-53 are pending in the present application.

The Examiner has required restriction between five groups:

Group I, claims 1-33 and 49-53, drawn to a method for the purification of an EGFR family derived protein.

Group II, claims 34, 35, and 45, drawn to immunogenic variant of HER-2 protein.

Group III, claims 36-44, and 46, drawn to a nucleic acid fragment that encodes the immunogenic variant of the HER-2 protein, vector comprising said fragment, and cell comprising said vector.

Group IV, claim 47, drawn to a method for immunizing a human against autologous HER-2 using the immunogenic variant of HER-2 protein.

Group V, claim 47, drawn to the method for immunizing a human against autologous HER-2 using the immunogenic vector comprising variant of HER-2 protein.

The Examiner states that “the inventions listed in Groups I-IV [V?] do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2 they lack the same or corresponding special technical features.” Applicants respectfully traverse.

**1. The Examiner Has Misinterpreted and Wrongly Applied PCT Rule 13.2**

Applicants submit that the Examiner has misinterpreted the requirements of PCT Rule 13.2. The Examiner has improperly focused on only the method for purification of the EGFR family derived proteins. In reply, Applicants submit that groups II-V are unitary and linked by a common general inventive concept.

Specifically, Group IV is unitary with Group II and Group V is unitary with Group III because Annex B of the PCT Administrative Instructions states:

The method for determining unity of invention under Rule 13.2 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application: (i) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of said product, and an independent claims for a use of said product . . . [is permitted].

(Annex B(e)(i))(attached). Applicants point out that the methods recited in groups IV and V are uses of the products of groups II and III, respectively. Therefore the methods of groups IV and V must be considered as unitary with the products of groups II and III, respectively. Applicants request that group II be rejoined with group IV and that group III be rejoined with group V.

Further, Applicants submit that claims II and III should be rejoined. Claim 34 (the “base claim” in group II) relates to a protein believed to be novel. Claim 36, from group III, relates to a nucleic acid which encodes the novel protein of claim 34. The PCT Administrative Instructions, Annex B, refers to specific examples which permit the prosecution of these two claims in the same application. (See, PCT Administrative Instructions, Annex B, Item I, page 96, Example 39) (attached). In Example 39, where “[t]he claimed DNA molecule encodes protein X,” and there is no prior art disclosing protein X, “therefore protein X and the DNA encoding protein X share a corresponding technical feature. Consequently the claims have unity of invention.” Therefore, since the protein of claim 34 is novel, the encoding nucleic acid should be rejoined (Claim 36).

Lastly, claims 10 and 11 relating to the purification of the HER-2 variant of group II are also unitary with group II, since the purification process in such a case is specially adapted for providing the protein of group II, as discussed above.

Thus Applicants request that groups II-V be rejoined, including claims 10 and 11.

**2. The Examiner Should Follow the International Examiner's Finding of Unity**

In making the restriction requirement, the Examiner has explained his reasoning by quoting from the International Examiner's IPER. But the International Examiner found that there was unity of invention. It is improper, and wholly inconsistent for the U.S. Examiner to not only follow, but even extensively quote the reasoning of the International Examiner, but then come to a completely contrary conclusion. The only explanation for this inconsistency is that the U.S. Examiner has improperly applied the standards for U.S. "restriction" practice rather than properly applying PCT Rule 13.1. Applicants submit that the U.S. Examiner should reach the same conclusion as the International Examiner, namely that there is unity of invention for all the claims.

**However, for the purposes of furthering prosecution, Applicants herein elect Group III, claims 36-44, and 46 (nucleic acid fragment encoding immunogenic variant of HER-2, vector comprising the fragment, and cell comprising the vector), with traverse.**

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard Svensson, Registration No. 30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

☒ Attached is a Petition for Extension of Time.

☒ Attached hereto is the fee transmittal listing the required fees.

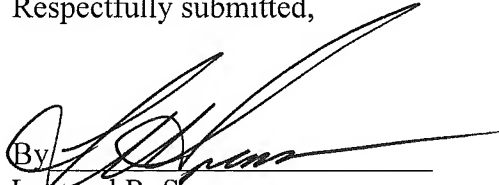
Application No.: 10/560,961

Docket No.: 4614-0182PUS1

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: August 26, 2008

Respectfully submitted,

By 

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Attachments:

- Annex B of the PCT Administrative Instructions
- Pages 91-96 of the Annex B, item 1 of the Administrative Instructions